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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 09/939,211 | 08/24/2001 | Daniel Lootz | 7040-40 | 3319 |
| 21324 | 7590 | 02/08/2006 | EXAMINER | |
| HAHN LOESER & PARKS, LLP | | | THALER, MICHAEL H | |
| One GOJO Plaza | | | ART UNIT | PAPER NUMBER |
| Suite 300 | | | | |
| AKRON, OH 44311-1076 | | | 3731 | |

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SIP

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/939,211 | LOOTZ ET AL. |
| | Examiner | Art Unit |
| | Michael Thaler | 3731 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 December 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,5,6,8-10,12-18,20,44,64,67,70,71,74-78,81,82,85,86,89,90,94,100 and 105-122 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,5,6,8-10,12-18,20,44,64,67,70,71,74-78,81,82,85,86,89,90,94,100 and 105-122.

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Claims 1, 5, 6, 8-10, 12-18, 20, 44, 64, 67, 70, 71, 74-78, 81, 82, 85, 86, 89, 90, 94, 100 and 105-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (6,190,406) in view of Wolinsky et al. (6,918,928). Duerig et al. disclose a plurality of annular support portions comprising bar elements 60 and connecting bars 70, wherein the connecting bars 70 engage in a region of the bar elements of the first annular support portion that projects in the longitudinal direction (in the embodiment described in col. 5, lines 46-53 in which one end is attached to the strut rather than the loop, noting that the entire strut projects in the longitudinal direction particularly in view of [0060] of applicant's specification which indicates that a portion of the bar element "projects less far in the first direction") and wherein the connecting bars engage a central portion of the second annular support portion (in the embodiment described in col. 5, lines 46-53 in which the other end is attached to the strut rather than the loop). Duerig et al. fail to disclose a direction of curvature changing in the central region of the bar element when the stent is in the first condition. However, Wolinsky et al. in figure 6 and col. 6, lines 17-42, for example, teach that the central region of a meandering bar element of a stent in the first, unexpanded condition, should be curved at inflection

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point 21 in order to obtain the advantage of enabling the links 25 to fit together more closely in a nested arrangement with the undulation of the rings 20a-c. It would have been obvious to incorporate this shape into the Duerig et al. bar element so that it too would have this advantage. Note that both Duerig et al. and Wolinsky et al. disclose adjacent bar elements that share a common turning point which do not converge at any point as the adjacent bar elements extend away from the common turning point as now claimed. As to claim 5, in the embodiment described in col. 5, lines 46-53 in which one end of the connecting bar 70 is attached to the strut rather than the loop, the connecting bars 70 engage the strut "near a turning point" as claimed since "near" is a relative term and any point on the strut is "near a turning point" as compared to other portions of the stent, for example. As to claims 6 and 114, Duerig et al. disclose an embodiment in which one end of the connecting bar 70 is attached to a strut and the other end is attached to a loop, noting the term "and/or" in reference to each end of the connecting bar in the phrase "wherein one end is attached to one strut and/or loop, and another end attached to a strut and/or loop on an adjacent hoop" in col. 5, lines 46-53. In this embodiment, the end of the connecting bar 70 that is attached to a loop "engages a point that projects furthest in the

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"longitudinal direction" as claimed, since figures 4 and 4a show the end of the connecting bar 70 attached to a loop at a point which projects furthest in the longitudinal direction even though it is attached slightly off center to the apex of the loop. In any event, the "point that projects furthest in the longitudinal direction" is considered to be the "turning point" which is considered to be the entire curved portion near the apex. As to claims 10, 105 and 121, note col. 7, lines 39-60 of Duerig et al. As to claim 16, for example, Duerig et al. fail to disclose the stent material in a stress-induced martensitic state at body temperature. However, it is old and well known in this art to design make shape memory alloys such that they are in a stress-induced martensitic state at body temperature in order to facilitate entry into the patient's body. It would have been obvious to make the Duerig et al. the stent material in a stress-induced martensitic state at body temperature so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03). As to claims 18, 85, 86, 90 and 119, the width of the Duerig et al. bar element varies over the length thereof (col. 6, lines 8-39). As to claims 94 and 100, the center line of the Duerig et al. bar element is in the shape of an elliptical arc

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in the region of the turning points when the stent is expanded, as seen in figure 5, for example.

Applicant's arguments filed Dec. 3, 2005 have been fully considered but they are not persuasive. Applicant argues on page 2 of the response that Wolinsky teaches that it is the approximate equality of the portion of the rings that extends in the circumferential direction at the inflection point to the width of the link (rather than the inflection point itself) that provides the advantageous nested arrangement (col. 6, lines 33-42). However, the inflection point itself is the feature which causes a portion of the rings to extend in the circumferential direction for a short distance (and produce an offset portion as described in col. 3, lines 43-47) and thus provide the advantageous nested arrangement. The "short portion of rings 20a-c at the inflection point which extends generally circumferentially" (col. 6, lines 34-36) having a length measured circumferentially which is about equal to the width of the link causes the advantageous nested arrangement according to Wolinsky. Applicant argues on pages 2 and 3 of the response that figures 2-4 of Duerig show that the stent adequately nests in the unexpanded state. This may be true for the embodiment shown in figures 2-4 of Duerig in which the connecting bars 70 are very short, are attached to the loops of the adjacent

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annular support portions 52 and thus do not extend between the bar elements 60 in a particular annular support portion. However, the embodiment of Duerig which the examiner relies upon is not shown in figures 2-4, but is the modification described in col. 5, lines 46-53 in which the ends of each connecting bar 70 are attached to the struts rather than the loops of the adjacent annular support portions 52. In this embodiment, the connecting bars 70 extend between the bar elements 60 in a particular annular support portion (similar to the embodiment shown in figures 3 and 6 of Wolinsky). Since the connecting bars 70 of Duerig, in this embodiment, extend between the bar elements 60, a nesting problem could exist without the inflection points 21. Finally, it should be noted that Wolinsky et al. alone, in figure 6, discloses all of the features in claim 1, for example.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will

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expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

mht
2/3/06



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731